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EXAMINER

WELLS, LAUREN Q

ART UNIT

PAPER NUMBER

1619

DATE MAILED: 01/03/2002

LS

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/468,777

Applicant(s)

HASEBE ET AL.

Examiner

Lauren Q Wells

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 20 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-19 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All   b) ☐ Some \*   c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8.                      6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

Claims 11-19 are pending. Claims 1-10 were cancelled by the Amendment received May 14, 2001 and claims 11-19 were added by the same Amendment.

#### ***Request for Continued Examination***

The request filed on November 20, 2001 for a Request for Continued Examination (RCE) under 37 CFR 1.114 based on parent Application No. 09/468,777 is acceptable and an RCE has been established. An action on the RCE follows.

#### ***Declaration***

The declaration under 37 CFR 1.132 filed November 20, 2001 is insufficient to overcome the rejection of claims 11-19 based upon the 35 USC 103(a) rejection as set forth in the last Office action because: the declaration compares the instant invention with comparative products containing no amphipathic lipid, but US 5,476,661, the primary reference in the 103 rejection, contains amphipathic lipid as an active ingredient.

In view of the foregoing, when all of the evidence is considered, the totality of the rebuttal evidence of nonobviousness fails to outweigh the evidence of obviousness.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 15 and 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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(i) The phrase "a substance analogous to ceramide" in claim 15 is vague and indefinite, as it is not clear what chemical compounds are encompassed by this phrase. The specification does not further define this phrase and one of ordinary skill in the art would not be apprised of these analogous substances.

(ii) The phrase "washing away type" in claims 17-19 (lines 1) is vague and indefinite, as it is not clear what compositions are encompassed by this phrase and it is not clear what properties this phrase is bestowing on a cosmetic composition.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Nakamura et al. (EP 0487958) in view of Vanlerberghe et al. (5,985,255) or Young (4,152,272).

Nakamura et al. teach cosmetic compositions comprising 0.05-30% of an amphiphatic lipid, 0.05-30% of a nonionic surfactant, 1-50% of an ionic surfactant, and 40-99% of an aqueous medium, in which the amphiphatic lipids are stably microdispersed. Ceramides are disclosed as suitable amphiphatic lipids. Suitable nonionic surfactants disclosed include polyoxyethylene sorbitan fatty acid ester and polyoxyethylene alkyl ether. The reference fails to teach the size of the amphiphatic lipid. See pg. 2, line 33-pg. 9, line 9.

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Vanlerberghe et al. teach cosmetic compositions for use as hair care products. Particles having an average diameter between 0.1-200  $\mu\text{m}$  are disclosed as known in the art. See Col. 1, line 8-Col. 2, line 11.

Young teach fabric conditioning compositions containing particles of 0.1-200 microns. Disclosed is an aqueous composition comprising wax-like substance and cationic surfactant. It is disclosed that although fabric softening compositions are highly preferred embodiments of the present invention, other types of products utilizing wax/perfume particles are possible, for example hair conditioners. See Col. 1, line 45-Col. 8, line 42.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Nakamura and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Nakamura teaches his dispersion as a microdispersion, wherein the definition of micro is 1.a. Small:

*microcircuit. b. Abnormally small: microcephaly. c. Requiring or involving microscopy: microsurgery.*

2. One-millionth ( $10^{-6}$ ): *microampere*.<sup>1</sup>; b) Nakamura teaches his amphiphatic lipids as ceramides, higher alcohols, glycolipids, and cholesterol, all of which can be characterized as waxes; c)

Young and Vanlerberghe teach aqueous dispersions comprising waxes, wherein the waxes have a particle size of between 0.1 and 200 microns; d) all three references teach compositions comprising wax constituents, surfactant and aqueous medium; e) all three references teach cosmetic embodiments of their compositions.

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Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dubief et al. (5,679,357) in view of Vanlerberghe et al. or Young.

Dubief et al. teach cationic dispersions based on ceramides and/or glycoceramides. Disclosed are compositions comprising ceramide and cationic surfactant in an aqueous medium. Ceramides and surfactants are disclosed as comprising 0.05-15% of the composition. The reference fails to teach the size of the amphiphatic lipid. See Col. 1, line 24-Col. 10, line 28.

Vanlerberghe et al. is applied as discussed above.

Young is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Dubief et al. and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Dubief teaches compositions comprising ceramides, which can be characterized as a wax; b) Young and Vanlerberghe teach aqueous dispersions comprising waxes, wherein the waxes have a particle size of between 0.1 and 200 microns; c) all three references teach compositions comprising wax constituents, surfactant and aqueous medium, and Dubief and Young both teach cationic surfactants; d) all three references teach cosmetic embodiments of their compositions; e) all three references specifically teach hair compositions as cosmetic embodiments.

Claims 11-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pillai et al. (5,476,661) in view of Vanlerberghe et al. or Young.

Pillai et al. teach cosmetic compositions for topical application to skin, hair, and nails. Amphipathic lipids are disclosed as comprising 0.0001-50% of the composition and surfactants

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are disclosed as comprising 0.5-30% of the compositions. Surfactants disclosed include alkoxylated compounds based upon fatty alcohols, fatty acids and sorbitan and alkyl polyglycosides. Dispersants are disclosed as cosmetic vehicles and water is exemplified as an aqueous vehicle. See Col. 4, line 24-Col. 11, line 61; Col. 13, line 45-line 67; Col. 22, line 30-Col. 25, line 3. The reference lacks teaching average particle size.

Vanlerberghe et al. is applied as discussed above.

Young is applied as discussed above.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the teachings of Vanlerberghe or Young into the invention of Pillai et al. and obtain a dispersion comprising amphiphatic lipid, surfactant, and an aqueous medium, wherein the lipid has an average particle size of 0.5-150um because a) Pillai teaches compositions comprising 25-OH-D3 and ceramides, both of which can be characterized as waxes; b) Young and Vanlerberghe teach aqueous dispersions comprising waxes, wherein the waxes have a particle size of between 0.1 and 200 microns; c) all three references teach compositions comprising wax constituents, surfactant and aqueous medium; d) all three references teach cosmetic embodiments of their compositions; e) all three references specifically teach hair compositions as cosmetic embodiments.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### ***Prior Art***

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not

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determined by the Examiner to read upon the invention currently being prosecuted in this application.


***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on T-F (6-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
December 18, 2001

  
DAMERON I. JONES  
PRIMARY EXAMINER